(i) Data derived from nonclinical laboratory and clinical studies that demonstrate that the manufactured product meets prescribed standards of safety, purity, and potency; with respect to each nonclinical laboratory study, either a statement that the study was conducted in compliance with the requirements set forth in part 58 of this chapter, or,

(ii) If the study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance;

(iii) Statements regarding each clinical investigation involving human subjects contained in the application, that it either was conducted in compliance with the requirements for institutional review set forth in part 56 of this chapter or was not subject to such requirements in accordance with §§56.104 or 56.105 of this chapter, and was conducted in compliance with requirements for informed consent set forth in part 50 of this chapter;

(iv) A full description of manufacturing methods;

(v) Data establishing stability of the product through the dating period;

(vi) Sample(s) representative of the product to be sold, bartered, or exchanged or offered, sent, carried or brought for sale, barter, or exchange;

(vii) Summaries of results of tests performed on the lot(s) represented by the submitted samples; and

(viii) Specimens of the labels, enclosures, and containers proposed to be used for the product.

(2) An application for license shall not be considered as filed until all pertinent information and data have been received from the applicant by the Center for Biologics Evaluation and Research. The applicant shall also include either a claim for categorical exclusion under §25.30 or 25.31 of this chapter or an environmental assessment under §25.40 of this chapter.

(3) Approval of the biologics license application and issuance of the biologics license shall constitute a determination that the establishment and the product meet applicable standards established in this chapter to ensure the continued safety, purity, and potency of such products. Applicable standards for the maintenance of establishments for the manufacture of a product subject to this paragraph (c) shall include the good manufacturing practice requirements set forth in parts 210 and 211 of this chapter. The following sections in parts 600 through 680 of this chapter shall not be applicable to such products: §§600.10(b) and (c), 600.11, 600.12, 600.13, 601.1, 610.11, 610.53, and 610.62 of this chapter.

(4) The term ''product license application,'' as it is used in those sections of parts 600 through 680 of this chapter that are applicable to products subject to this paragraph (c) shall include a biologics license application for a therapeutic DNA plasmid product, therapeutic synthetic peptide product of 40 or fewer amino acids, monoclonal antibody product for in vivo use, or therapeutic recombinant DNA-derived product.

(5) To the extent that the requirements in this paragraph (c) conflict with other requirements in this subchapter, this paragraph (c) shall supersede such other requirements.

(6) The applicant, or the applicant's attorney, agent, or other authorized official shall sign the application.

[40 FR 31313, July 25, 1975, as amended at 46 FR 8955, Jan. 27, 1981; 47 FR 6618, Feb. 16, 1982; 49 FR 23833, June 8, 1984; 50 FR 7518, Feb. 22, 1985; 50 FR 16669, Apr. 26, 1985; 55 FR 11013 and 11014, Mar. 26, 1990; 61 FR 24232, May 14, 1996; 62 FR 11769, Mar. 13, 1997; 62 FR 40600, July 29, 1997; 62 FR 53538, Oct. 15, 1997; 63 FR 5253, Feb. 2, 1998]

EFFECTIVE DATE NOTE: At 63 FR 5253, Feb. 2, 1998, §601.2 was amended in paragraph (a) by adding a sentence after the first sentence, effective Feb. 2, 1999.

§601.3 License forms.

(a) *Establishment license.* The establishment license form shall be prescribed by the Director, Center for Biologics Evaluation and Research and shall include:

(1) The name and address of the manufacturer.

(2) The name and address of the establishment.

(3) The names and addresses of all locations of the establishment.

(4) The license number.

(5) The date of issuance.

(b) *Product license.* The product license form shall be prescribed by the

Director, Center for Biologics Evaluation and Research and shall include:

(1) The name and address of the manufacturer.

(2) The name and address of the establishment.

(3) The name and address of each location at which the product is manufactured.

(4) The license number of the establishment.

(5) The proper name of the product, with additional specifications, if any, which may be approved or required for additional labeling purposes.

[38 FR 32052, Nov. 20, 1973, as amended at 49 FR 23833, June 8, 1984; 55 FR 11013, Mar. 26, 1990]

§ 601.4 Issuance and denial of license.

(a) An establishment or product license shall be issued upon a determination by the Director, Center for Biologics Evaluation and Research that the establishment or the product, as the case may be, meets the applicable standards established in this chapter. Licenses shall be valid until suspended or revoked.

(b) If the Commissioner determines that the establishment or product does not meet the standards established in this chapter, he shall deny the application and inform the applicant of the grounds for, and of an opportunity for a hearing on, his decision. If the applicant so requests, the Commissioner shall issue a notice of opportunity for hearing on the matter pursuant to § 12.21(b) of this chapter.

[42 FR 4718, Jan. 25, 1977, as amended at 42 FR 15676, Mar. 22, 1977; 42 FR 19142, Apr. 12, 1977; 49 FR 23833, June 8, 1984; 55 FR 11013, Mar. 26, 1990]

§ 601.5 Revocation of license.

(a) An establishment or product license shall be revoked upon application of the manufacturer giving notice of intention to discontinue the manufacture of all products or to discontinue the manufacture of a particular product for which a license is held, and waiving an opportunity for a hearing on the matter.

(b) If the Commissioner finds that (1) authorized Food and Drug Administration employees after reasonable efforts have been unable to gain access to an establishment or a location for the purpose of carrying out the inspection required under § 600.21 of this chapter, (2) manufacturing of products or of a product has been discontinued to an extent that a meaningful inspection or evaluation cannot be made, (3) the manufacturer has failed to report a change as required by § 601.12, (4) the establishment or any location thereof, or the product for which the license has been issued, fails to conform to the applicable standards established in the license and in this chapter designed to ensure the continued safety, purity, and potency of the manufactured product, (5) the establishment or the manufacturing methods have been so changed as to require a new showing that the establishment or product meets the standards established in this chapter in order to protect the public health, or (6) the licensed product is not safe and effective for all of its intended uses or is misbranded with respect to any such use, he shall notify the licensee of his intention to revoke the license, setting forth the grounds for, and offering an opportunity for a hearing on, the proposed revocation. Except as provided in § 601.6 or in cases involving willfulness, the notification required in this paragraph shall provide a reasonable period for the licensee to demonstrate or achieve compliance with the requirements of this chapter, before proceedings will be instituted for the revocation of the license. If compliance is not demonstrated or achieved and the licensee does not waive the opportunity for a hearing, the Commissioner shall issue a notice of opportunity for hearing on the matter pursuant to § 12.21(b) of this chapter.

[42 FR 4718, Jan. 25, 1977, as amended at 42 FR 15676, Mar. 22, 1977; 42 FR 19143, Apr. 12, 1977; 49 FR 23833, June 8, 1984]

§ 601.6 Suspension of license.

(a) Whenever the Commissioner has reasonable grounds to believe that any of the grounds for revocation of a license exist and that by reason thereof there is a danger to health, he may notify the licensee that his license for the establishment or the product is suspended and require that the licensee (1) notify the selling agents and distributors to whom such product or products